Remarks

Amendments to the Specification

Applicants have amended the specification to remove a hyperlink, to introduce sequence identifiers, and to correct typographical errors. The amendments add no new matter to the application.

Amendments to the Sequence Listing

Applicants have added a sequence listing to the application. Support for the sequence listing is found in the sequences present in the application as originally filed. As such, entry of the sequence listing adds no new matter to the application.

Amendments to the Claims

Claims 1-20 were pending.

Applicants have canceled claims 3-4, 7-13 and 15-20 without prejudice to Applicants' right to pursue their subject matter in the present application and in related applications.

Applicants have amended claim 1 to recite a method for identifying a subject at risk of developing hypertensive end organ damage or complications of hypertensive end organ damage, comprising detecting the level of galectin-3 in a biological sample from a human subject and comparing the level of galectin-3 to a standard level indicative of risk of developing hypertensive end organ damage or complications of hypertensive end organ damage, and to delete unnecessary words. Support for the amendments to claim 1 are found in the original application at, for example, pages 1, 2 and 4 and in original claims 1 and 4. Applicants have amended claim 2 to recite "serum or plasma"; support for the amendment is found in the original application at, for example, page 4, line 25. Applicants have amended claim 4 to recite further comprising comparing the level of thrombospondin-2 in the sample to a standard level indicative of hypertensive end organ damage risk; support for the amendment is found in the original application at, for example, pages 2 and 4 and in original claim 1. Applicants have amended claims 6 and 14 for consistency with amended claim 1, from which they depend.

Applicants have introduced new claims 21-33. Support for new claim 21 is found in the original application at, for example, pages 2 and 4. Support for new claims 22 and 27 is found in the original application at, for example, Example 3. Support for new claims 23 and 29 is found in the original application at, for example, pages 1, 2 and 4, Example 3, and original claims 1 and 4. Support for new claims 24 and 30 is found, for example, in original claim 2. Support for new claims 25 and 31 is found in the original application at, for example, pages 1, 2, and 4 and in Example 3. Support for new claims 26 and 32 is found in the original application at, for example, page 4, lines 16-20, in Example 3, and in original claim 4. Support for new claims 28 and 33 is found in the original application at, for example, page 5, lines 23-24.

These amendments introduce no new matter into the application. Upon entry of the present amendment, claims 1-2, 5-6, 14, and 21-33 will be pending and presented for consideration.

Sequence Compliance

Applicants have now provided a sequence listing complying with 37 C.F.R. § 1,821 *et seq.* and have amended the specification to introduce sequence identifiers.

Objection to the Specification

The Office action objected to the specification as containing a hyperlink. Applicants have amended the specification to remove the hyperlink and request withdrawal of the objection.

Objections to the Claims

The Office action objected to claim 1 as containing a sentence fragment and recommended amending claim 1 to recite that the marker is indicative of a risk of developing hypertensive end organ damage.

Applicants request withdrawal of the objection in view of the amendments to claim 1.

The Office action also objected to claim 7. Applicants request withdrawal of the objection in view of the cancellation of the claim.

Rejections under 35 U.S.C. 112, 2nd paragraph and under 35 U.S.C. § 101

The Office action rejected claim 1 under the second paragraph of 35 U.S.C. § 112 as allegedly indefinite for reciting "determining." Applicants disagree that the term is indefinite but, to advance prosecution, have replaced it with "detecting" as recommended in the action. The Office action also alleged that "determining whether the level of the marker is indicative of risk" was indefinite. Applicants have canceled that clause from the claim without prejudice to Applicants' right to pursue its subject matter in the present claims and in related applications.

Applicants request that the rejection of claim 1 be reconsidered and withdrawn.

The Office action also rejected claims 7-12 and 18 under the second paragraph of 35 U.S.C. § 112 and/or under 35 U.S.C. § 101. Applicants have canceled claims 7-12 and 18 and request that the rejections accordingly be withdrawn.

U.S. Patent Application Publication No. US 2002/0076738 (Woo)

The Office action rejected claims 1, 3, 4, 6, 15, 16 and 18 under 35 U.S.C, § 102 as allegedly anticipated by Woo.

Applicants disagree.

A prior art reference does not anticipate unless it discloses "within the four corners of the document not only all of the limitations claimed but also all of the limitations combined in the same way as recited in the claim." *NetMoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008).

The invention of claim 1 relates to a method for identifying a subject at risk of developing hypertensive end organ damage or complications of hypertensive end organ damage. Woo does not disclose a method for identifying a subject at risk of developing hypertensive end organ damage or complications of hypertensive end organ damage. Indeed, Woo is completely silent regarding hypertensive end organ damage. Rather, Woo relates to a "Method and Kit for Predicting Cancer" (Woo, title). Cancer is not hypertensive end organ damage. Because Woo

does not teach a method for identifying a subject at risk of developing hypertensive end organ damage or complications of hypertensive end organ damage, Woo does not disclose all of the limitations of claim 1 and cannot anticipate the invention of claim 1.

Furthermore, Applicants have now amended claim 1 to recite determining the level of galectin-3 in a biological sample from a human subject and comparing it to a *standard level indicative of risk of developing hypertensive end organ damage or complications of hypertensive end organ damage*. Woo does not teach comparison to a standard level indicative of risk of developing hypertensive end organ damage or complications of hypertensive end organ damage and therefore cannot anticipate claim 1.

Woo also fails to anticipate new independent claim 23, relating to a method for identifying a subject at risk of developing heart failure or developing complications of heart failure—which Woo does not teach—comprising comparing the level of galectin-3 to a standard level indicative of heart failure risk—which Woo does not teach.

Woo similarly fails to anticipate new independent claim 29, relating to a method of identifying a risk of developing congestive heart failure or developing complications of congestive heart failure—which Woo does not teach—in a patient with cardiovascular disease—which Woo does not teach—comprising comparing the level of galectin-3 to a standard level indicative of a risk of developing congestive heart failure or developing complications of congestive heart failure—which Woo does not teach.

Applicants therefore request that all rejections based on Woo be reconsidered and withdrawn.

U.S. Patent Application Publication Nos. US 2006/0166276 (Doyle) and US 2003/0166017 (McCarthy)

The Office action rejected claims 1-3, 6-8, 13-15 and 19-20 under 35 U.S.C. § 102(e) as allegedly anticipated by Doyle. The Office action also rejected claims 1-3, 5-6, 13-15 and 17-20 under 35 U.S.C. § 102(e) as allegedly anticipated by McCarthy.

Applicants note that claim 4, which recited galectin-3, was not alleged to be anticipated either by Doyle or by McCarthy.

The amended claims require detecting or measuring galectin-3. Neither Doyle nor McCarthy discloses detecting or measuring galectin-3. Accordingly, neither Doyle nor McCarthy anticipates any of the pending claims. Applicants therefore request that all rejections based on Doyle or McCarthy be reconsidered and withdrawn.

Conclusion

Applicants believe the claims are in condition for allowance. Applicants invite the Examiner to contact the undersigned Attorney regarding any remaining issues.

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